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10/528,957	03/22/2005	Ian Flockhart	B0192.70056US00	8763
23628 7590 04/30/2008 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER KEYS, ROSALYND ANN	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,957	<b>Applicant(s)</b> FLOCKHART ET AL.	
	<b>Examiner</b> ROSALYND KEYS	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8, 10-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 10-23 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-4, 6-8, 10-23 and 25 are pending.  
Claims 1-4, 6-8, 10-23 and 25 are rejected.  
Claims 5, 9, and 24 are cancelled.

### ***Response to Amendment***

#### *Claim Rejections - 35 USC § 112*

2. The rejection of claims 2, 4, 18, 21 and 22 under 35 U.S.C. 112, second paragraph, is withdrawn, due to the amendment to said claims, filed February 12, 2008.

#### *Claim Rejections - 35 USC § 103*

3. The rejection of claims 1-4, 6-8, 10-13, 18-23 and 25 under 35 U.S.C. 103(a) as being unpatentable over Webster et al. (US 6,403,126 B1) alone or in view of Adams (US 2,304,669) and further in view of Schmidt et al. (US 2003/0017216 A1) is withdrawn, due to the amendment filed February 12, 2008. However, a new rejection over the same art is presented below as well as arguments as to why said references are still applicable.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-4, 6-8, 10-23 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

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the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitations "selectively isolating the cannabidiol" in step (b) and "selectively isolate" in step (c) are not supported in the original specification. The original specification describes "selectively preparing" substantially pure cannabidiol (see paragraph 0020). One having ordinary skill in the art would not associate preparing and isolating as having the same meaning.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-4, 6-8, 10-13, 18-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster et al. (US 6,403,126 B1) alone or in view of Adams (US 2,304,669) and further in view of Schmidt et al. (US 2003/0017216 A1).

Webster et al. teach a method for producing a purified cannabinoid which comprises a) obtaining an extract by extracting chaff, which is chopped plant material, with a solvent; passing the extract over a column arranged to fractionate the desired cannabinoid; the desired cannabinoid is eluted from the column and purified by b) extraction of the eluted cannabinoid or (c) concentrating the eluted cannabinoid (see entire disclosure, in particular column 2, line 40 to column 3, line 20; column 3, line 61 to column 6, line 39). In example I Webster teaches separation of liquid extract from the solid component by filtration or other means known in the art and concentrating the extract and resuspending it in a new solvent. Example II discloses isolation of the individual components by HPLC and the fractions are further concentrated by evaporation to yield extracts which are suitable for further treatments by means known in the art. Alternatively the fractions are crystallized as a means of isolation. Use of other solvents is also disclosed in Example II as a means for isolation. The extraction solvent may be an organic solvent, which may be selected from a petroleum derived hydrocarbon or supercritical carbon dioxide (see column 2, lines 24-32). The cannabinoid may be selected from cannabidiol (see column 2, lines 56-63 and column 5, lines 14-18).

Webster et al. differ from the instant claims in that although Webster et al. teach steps a), b) and c) individually as a means of obtaining purified cannabidiol, Webster et al. do not require that each step be performed in order to isolate the purified cannabinoid. However, the instant claims are nonetheless obvious over the teachings of Webster et al. because the ordinary skilled artisan would have found it obvious to combine any of the individual isolation steps disclosed by

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Webster et al. with a reasonable expectation of obtaining a purified cannabinoid. "A person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." KSR International Co. v. Teleflex Inc., 550 U.S.\_\_\_\_, 82 USPQ2d 1385, 1395-97 (2007).

Webster et al. differ from the instant claims in that Webster et al. do not disclose the purity of their cannabinoids. However, Webster et al. do suggest the claimed purity, since Webster et al. teach that the individual components may be isolated by subjecting the extract to HPLC (see column 5, lines 62-64). Further, when claiming a purer form of a known compound, it must be demonstrated that the purified material possess properties and utilities not possessed by the unpurified material. Ex parte Reed, 135 U.S.P.Q. 34, 36 (P.O.B.A. 1961), on reconsideration, Ex parte Reed, 135 U.S.P.Q. 105 (P.O.B.A. 1961). In the instant case the cannabidiol does not appear to have a property or utility not possessed by the cannabidiol of Webster et al.

Webster et al. further differ from the instant claims in the Webster et al. do not disclose the melting point of the crystalline cannabidiol.

Adams discloses that one can obtain a pure crystalline cannabidiol from extracts of hemp (see column 1, lines 1-19). It is taught that the Cannabidiol has a melting point of 66-67° (see column 1, lines 25-27).

One having ordinary skill in the art at the time the invention was made would have found it obvious that the crystalline cannabidiol of Webster has a melting point of 66-67°, since Adams teaches that crystalline cannabidiol has a melting point of 66-67°.

Webster et al. further differ from the claims in that Webster et al. do not specifically disclose utilizing pentane as the solvent. However, Webster et al. do suggest the use of pentane, since Webster et al. disclose the use of a petroleum-derived hydrocarbon as a solvent (see column 4, lines 26-48, in particular lines 37 and 38).

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Webster et al. further differ from the instant claims in that Webster et al. do not specifically disclose an initial extraction with liquid carbon dioxide followed by a secondary extraction with another solvent such as ethanol. Webster et al. do however teach that other solvents may be used as modifiers in combination with the supercritical fluid for targeted extraction of specific compounds (see example I). Webster et al. also teach that the extract may be suspended in another suitable solvent such as low molecular weight alcohol (see column 2, line 33-48).

Schmidt et al. teach that changing the polarity and hydrophilicity of the extracting solvent systems can modify the ratio of components in the Cannabis oil (see paragraph 0014).

One having ordinary skill in the art at the time the invention was made would have found it obvious to extract the Cannabis of Webster et al. with a combination of a supercritical fluid such as carbon dioxide and another solvent such as ethanol, since Webster et al. teach that combinations of solvent may be utilized for extraction. Further the skilled artisan would be motivated to select the combination of solvents in order to modify the ratio of components in the Cannabis oil, as taught by Schmidt et al.

Webster et al. further differ from the claims in that Webster et al. do not teach a charcoal cleanup step.

Schmidt et al. teach that techniques known to the art such as steam distillation or activated charcoal filtration may optionally be utilized to further enrich the cannabinoid fraction of extracts (see paragraph 0018).

One having ordinary skill in the art at the time the invention was made would have been motivated to utilize a technique such as activated charcoal filtration, as taught by Schmidt et al., on the cannabinoid of Webster et al. in order to obtain a further enriched cannabinoid fraction for medicinal use.

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10. Claims 1-4, 6-8, 10-13, 18-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whittle et al. (WO 02/064109 A2) in view of Webster et al. (US 6,403,126 B1) and further in view of Schmidt et al. (US 2003/0017216 A1) and Adams et al.(US 2,304,669), for essentially the same reasons as the previous office action, mailed October 18, 2007.

Whittle et al. teach a method of preparing an herbal drug extract comprising obtaining medicinal cannabis, chopping the cannabis, heating at a temperature of 100 to 150°C for sufficient time to decarboxylate acid form of cannabinoids to produce neutral cannabinoids, extraction with liquid carbon dioxide, removal of carbon dioxide to recover crude extract, winterization of crude extract in ethanol to precipitate unwanted waxes, removal of unwanted waxy material by cold filtration and removal of ethanol from the filtrate by thin film evaporation under reduced pressure (see example 17 on pages 63 and 64). Whittle et al. teach that one can obtain an extract from a chemovar of cannabis producing more than 90% of its cannabinoid as cannabidiol by supercritical fluid extraction of dried cannabis herb (see page 42, lines 9-13).

Whittle et al. differ from the instant claims in that Whittle et al. do not teach the use of a C5-C12 straight chain or branched alkane or a carbonate ester of a C1-C12 alcohol to selectively isolate the cannabidiol.

Webster et al. teach a process for extraction of a cannabinoid wherein petroleum derived hydrocarbon, such as trimethylpentane is interchangeable as an extraction solvent with low molecular weight alcohols, such as ethanol (see column 3, lines 1-9 and column 4, lines 26-48). Example I also discloses that hexane and ethanol are interchangeable as extraction solvents.

One having ordinary skill in the art at the time the invention was made would have found it obvious to substitute a petroleum-derived hydrocarbon, as taught by Webster et al., for the low molecular alcohol of Whittle et al., since Webster et al. teach that in a process for the



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extraction of cannabinoids one can use petroleum derived hydrocarbons and low molecular weights alcohols interchangeably.

Whittle et al. further differ from the claims in that Whittle et al. do not teach treatment of the resulting solution with activated charcoal.

Schmidt et al. teach that techniques known to the art such as steam distillation or activated charcoal filtration may optionally be utilized to further enrich a cannabinoid fraction of extracts (see paragraphs, 0007 and 0018).

One having ordinary skill in the art at the time the invention was made would have been motivated to utilize a technique such as activated charcoal filtration, as taught by Schmidt et al., on the cannabinoid of Whittle et al. in order to obtain a further enriched cannabinoid fraction, which is valuable since the cannabinoid has medicinal use.

Whittle et al. further differ from the claims in that Whittle et al. do not teach that their cannabidiol comprise less than 1%  $\Delta^9$  THC.

Webster et al. teach that Cannabis contains a high level of  $\Delta^9$  THC which is a psychoactive drug (see column 1, lines 15-43). Webster et al. teach that  $\Delta^9$  THC can be removed from the cannabinoid utilizing the steps of their invention.

One having ordinary skill in the art at the time the invention was made would have found it obvious that the  $\Delta^9$  THC is removed in the process of Whittle et al., since Whittle et al. conduct some of the same steps utilized in the process of Webster et al.

Whittle et al. do not disclose the melting point or CBD retention time of their cannabidiol. However, since the cannabidiol of Whittle et al. appears to be identical to the claimed cannabidiol it would inherently have the same melting point (66-67°C as taught in column 1, lines 25 and 26 of Adams et al.) and CBD retention time.

**Response to Arguments**

Rejection of claims 1-4, 6-8, 10-13, 18-23 and 25 under 35 U.S.C. 103(a) as being unpatentable over Webster et al. (US 6,403,126 B1) alone or in view of Adams (US 2,304,669) and further in view of Schmidt et al. (US 2003/0017216 A1)

11. Applicant's arguments filed February 12, 2008 have been fully considered but they are not persuasive.

The Applicants argue that there is no suggestion that the "Cannabis extract" according to the first aspect of Webster is a cannabinoid, pure or otherwise.

This argument is not persuasive because in column 3, lines 61-63 Webster discloses that described herein is a method of processing Cannabis and extracting cannabinoids, cannaflavins or essential oils therefrom. The cannabinoids that may be extracted from the Cannabis besides the  $\Delta^9$ -THC include cannabidiol (see column 2, lines 56-63). As one can clearly see the first and fourth aspects of the invention include the same steps for obtaining an extract, i.e., harvesting Cannabis composed of seed and chaff; separating the chaff from the seed; extracting the chaff with a solvent, thereby producing an extract. Thus, one having ordinary skill in the art would reasonably believe that, prior to the fractionation step, the extract obtained in the first aspect of the invention has the same composition as the extract obtained in the fourth aspect of the invention.

The Applicants argue that, as the Examiner has recognized, this process produces a "whole hemp extract without the  $\Delta^9$ -THC.

This argument is not persuasive because column 2, lines 17 to 18 refer to the whole hemp extract that has been passed over a chromatographic column in order to remove the  $\Delta^9$ -THC contained therein. The extract obtained from the extraction process prior to passing it over the chromatographic column does contain  $\Delta^9$ -THC as well as the other cannabinoids mentioned therein (see column 2, lines 13-63).

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The Applicants argue that this process does not provide the features of the process described in claim 1, since it does not result in the production of purified CBD, but rather a "whole hemp extract".

This argument is not persuasive because the Applicants are trying to limit the teachings of Webster to just the first aspect of the invention instead of what it teaches those of ordinary skill in the art. A prior art disclosure is not limited to its working examples or to its preferred embodiments, but must be evaluated for what it teaches those of ordinary skill in the art. Merck & Co. Inc. v. Biocraft Labs. Inc., 874 F.2d 804, 807, 10 USPQ2d 1843, 1846 (Fed. Cir. 1989); In re Fracalossi, 681 F.2d 792, 794 n.1, 215 USPQ 569, 570 n.1 (CCPA 1982); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976); In re Boe, 355 F. 2d 961, 965, 148 USPQ 507, 510 (CCPA 1966). All aspects of Webster's invention is part of the prior art. In column 2, lines 50-52 Webster teaches that a purified cannabinoid may be obtained. In column 2, lines 55 and 56 cannabidiol is disclosed as one such cannabinoid.

The Applicants argue that furthermore there is no mention of the use of a non-polar solvent which is a C5-C12 straight chain or branched chain alkane or a carbonate ester of a C1-C12 alcohol for the selective isolation of cannadibiol from plant material.

This argument is not persuasive because Webster teaches extracting the chaff, which refers to the chopped plant material remaining after the seed of the hemp has been harvested and separated (see column 3, lines 37-39) , with a solvent (see column 2, lines 11 and 12 and lines 45 and 46). Suitable solvents include a petroleum derived hydrocarbon, such as trimethylpentane, which is a C8 branched chain alkane (see column 2, lines 24-26). In example I hexane is used as the extraction solvent. In column 5, lines 14-40 Webster teaches that one can arrange the column to fractionate a specific cannabinoid. Webster further teaches that the compound(s) of interest are retained or detained on the column so that the last fractions of the extract eluted from the column contain the compound(s) of interest. The fractions containing

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the compound(s) of interest are pooled. In some embodiments, different compounds may be extracted with different solvents and then combined into a single extract. Webster then teaches that several different cannabinoids could be purified from a single extract. Further in example I Webster teaches extracting with solvent for a period of time. The liquid is then separated from the solid component, by filtration or other means known in the art. At this point, the extract may be concentrated or dried and resuspended in a new solvent. At the conclusion of the example Webster teaches that other solvents may be used as modifiers in combination with supercritical fluid for targeted extraction of specific compounds, as discussed above. The Examiner believes that from the teaching of Webster one having ordinary skill in the art would reasonably believe that Webster teaches or at least fairly suggests that one can isolate a specific cannabinoid (selectively isolate), including the claimed cannabidiol from a plant material using solvent extraction and/or crystallization.

The Applicants argue that the first aspect of Webster and exemplified in Example I would not result in selective isolation of substantially pure cannabidiol as required by claim 1. The Applicants further argue that the disclosure of Webster confirms that fractionation techniques such as HPLC should be used to isolate individual components of the whole hemp extract.

Before addressing these arguments the Examiner wishing to point out that Applicants greater than 95% purity is a chromatographic purity (see paragraphs 0019, 0022, 0062 and 00690072). Nonetheless, Applicants obtain their purified CBD by a method **comprising**

(a) obtaining a cannabidiol-containing primary extract of a plant material by maceration, percolation or solvent extract and optionally conducting a further secondary solvent extraction step to obtain a secondary extract

(b) selectively isolating the cannabidiol by dissolving the primary or secondary extract obtained in (a) in a non-polar solvent which is a C5-C12 straight chain or branched alkane or a carbonate ester of a C1-C12 alcohol to form a solution; and

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(c) removing insoluble material from the solution by filtration and evaporating the solvent from the solution to selectively isolate the substantially pure cannabidiol.

Correspondingly Webster obtains purified CBD by a method comprising

- a) obtain an extract by extracting chaff, chopped plant material, with a solvent
- arranging the column to fractionate the desired cannabinoid
- the desired cannabinoid is eluted from the column and purified by
- b) extraction of the eluted cannabinoid or
- (c) concentrating the eluted cannabinoid (see column 5, lines 3-40).

In example I Webster teaches separation of liquid extract from the solid component by filtration or other means known in the art and concentrating the extract and resuspending it in a new solvent. Example II discloses concentration by evaporation and also discloses crystallization as a means of isolation.

The applicants use of the transitional phrase comprising allows for other steps in addition to steps (a) to (c) disclosed in claim 1. Thus, the claims do not exclude the fractionating step disclosed by Webster. Webster teaches that various modifications may be made to the process (see column 6, lines 40-44). Thus, one having ordinary skill in the art would have found it obvious that any of the isolation techniques taught by Webster may be used to obtain the desired purified cannabinoid. The skilled artisan would reasonably expect that the use of a combination of the isolation techniques disclosed by Webster would result in a more purified cannabinoid. The claimed invention would have been obvious because "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *KSR International Co. v. Teleflex Inc.*, 550 U.S.\_\_\_\_, 82 USPQ2d 1385, 1395-97 (2007).

The Applicants arguments regarding the fractionation step and use of a chromatographic column being an essential feature of Webster are not persuasive because as

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pointed out above the instant claims do not exclude the presence of a fractionation step or use of a chromatographic column.

The Applicants submit that Example I of Webster is not a method that selectively isolates substantially purified cannabidiol as is claimed by Applicant.

This argument is not persuasive because in Example I it is disclosed that in some embodiments, the foliar and floral material from the hemp may be subjected to supercritical fluid extraction for extracting cannabinoids. It is also taught in Example I that other solvents may be used as modifiers in combination with the supercritical fluid for targeted extraction of specific compounds. Thus, the Examiner believes that there is at least a suggestion to obtain a specific cannabinoid, including the claimed CBD, by extraction.

The Applicants argue that Webster contains no teaching that would enable the skilled person to produce purified cannabidiol based on solvent extraction alone.

This argument is not persuasive because the claims do not require the use of solvent extraction alone. Other forms of isolation may be utilized.

The Applicants argue that absolutely no teaching is given regarding selective isolation of CBD from plant material as is claimed in amended claim 1.

This argument is not persuasive because Webster teaches extracting a cannabinoid from chaff, which is a plant material.

The Applicants argue that the claims as amended exclude fractionation of the extract obtained in step (a), since the wording of (b) demands that the extract obtained in (a) is dissolved in a C5-C12 straight chain or branched alkane or carbonate ester of a C1-C12 alcohol to form a solution and that similarly step (c) requires that this solution is filtered, excluding an intermediary fractionation step.

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These arguments are not persuasive because the claims still include the transitional phrase comprising in the preamble which allows for the presence of other steps in the claimed method. Therefore the amendments have not excluded the presence of a fractionation step.

For the above reasons the claimed invention is not patentable over Webster et al. (US 6,403,126 B1) alone or in view of Adams (US 2,304,669) and further in view of Schmidt et al. (US 2003/0017216 A1).

Rejection of claims 1-4, 6-8, 10-13, 18-23 and 25 under 35 U.S.C. 103(a) as being unpatentable over Whittle et al. (WO 02/064109 A2) in view of Webster et al. (US 6,403,126 B1) and further in view of Schmidt et al. (US 2003/0017216 A1) and Adams et al. (US 2,304,669)

12. Applicant's arguments filed February 12, 2008 have been fully considered but they are not persuasive.

The Applicants argue that there is no teaching in Webster of Whittle that indicates that a C5-C12 straight chain or branched chain alkane or a carbonate ester of a C1-C12 alcohol may be used to selectively isolate cannabidiol from an initial crude or whole extract of cannabis plant material.

This argument is not persuasive because Whittle teaches the use of ethanol to dissolve the crude extract. Webster teaches that solvents such as trimethylpentane and hexane are interchangeable with ethanol as an extraction solvent. One having ordinary skill in the art at the time the invention was made would have found it obvious to use a C5-C12 straight chain or branched chain alkane for isolation of a cannabidiol, since Webster teaches that trimethylpentane and hexane are suitable extraction solvents extracting cannabinoids. The skilled artisan would have found it obvious to than use said C5-C12 straight chain or branched chain alkane in place of the ethanol for isolation of the cannabidiol in Whittle, since Webster

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teaches that ethanol is interchangeable as an extraction solvent with trimethylpentane and hexane.

The Applicants argue that unlike Webster the current claims do not encompass a method in which the solvent specified in step (b) is to be used at the same time as any solvent extraction used in step (a).

This argument is not persuasive because Webster is the secondary reference. The primary reference Whittle does teach a method in which a solvent (ethanol) is used in addition to the solvent extraction step (see page 64 of Whittle).

The Applicants argue that the instant claim 1 as amended relies on a combination of solvent extraction steps, not fractionation as taught in Webster.

This argument is not persuasive because again Webster is the secondary reference. The primary reference Whittle does teach a method wherein a combination of solvent extraction steps are utilized (again see page 64 of Whittle).

The Applicants arguments that the combination of references contains no teaching that would enable the skilled person to produce purified cannabidiol based on solvent extraction alone is not persuasive because the claims are not limited to the use of solvent extraction alone.

The Applicants argue that absolutely no teaching is given regarding selective isolation of CBD from plant material as is claimed in amended claim 1.

The Examiner disagrees and believes that the combination of Whittle with Webster would lead to the selective isolation of CBD from plant material as is claimed, since Whittle utilizes essentially the same steps as the claimed invention with the exception of the use of a different extraction solvent, which is instead taught by Webster.



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The Examiner believes that Schmidt and Adams provide the features that are lacking in Webster and Whittle for the reasons of record.

For the above reasons the instant claims 1-4, 6-8, 10-13, 18-23 and 25 are unpatentable under 35 U.S.C. 103(a) over Whittle et al. (WO 02/064109 A2) in view of Webster et al. (US 6,403,126 B1) and further in view of Schmidt et al. (US 2003/0017216 A1) and Adams et al. (US 2,304,669).

### **Conclusion**

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROSALYND KEYS whose telephone number is (571)272-0639. The examiner can normally be reached on M, R & F 5:30-7:30 am & 1-5 pm; T & W 5:30 am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/ROSALYND KEYS/  
Primary Examiner, Art Unit 1621

April 24, 2008